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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,334	10/18/1999	STEVEN D. LACY	98-11CIP1RCE	2647

22905 7590 08/28/2006

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/420,334	LACY ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,12-14,19,23,24,27,29,37,39-45,48-50,55,59,60,63,65,92,94,95,97,99 and 100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3-9,12-14,19,23,24,27,29,37,39-45,48-50,55,59,60,63,65,92,94,95,97,99 and 100.

DETAILED ACTION

Applicant's arguments, filed 5/23/2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

It is acknowledged that claims 11, 21-22, 47, 57-58, 91, 93, 96, and 98 have been cancelled without prejudice in response to the non-final rejection office action mailed out on 1/19/2006.

It is acknowledged that in response to the non-final rejection office action mailed out on 1/19/2006, applicants have amended their claims 1, 5, 12-14, 19, 37, 41, 48-50, 55, 94, and 99. Therefore, rejections made in the instant office action have been necessitated by amendment.

Claims 1, 3-9, 12-14, 19, 23-24, 27, 29, 37, 39-45, 48-50, 55, 59-60, 63, 65, 92, 94-95, 97, and 99-100 is the instant claim set hereby under examination.

New Rejections

As stated above, the following rejections are necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 19, 23-24, 27, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 55 state that the chemicals to be assigned to the given cell are "determined by the one or more sources," which has been deemed as vague and indefinite. Do the sources that represent the one or more chemicals determine the chemicals to be assigned to the given cells or does the user input and solving the plurality of equations determine the chemicals to be assigned to the given cell?

Claims 23-24, 27, 29, 59-60, 63, 65, 92, 94-95, 97, and 99-100 are rejected as being dependent from a rejected claim.

Response to Arguments

Claim Rejections - 35 USC § 102

Maintained with respect to the following claims

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 12-14, 37, 39-43, 45, 48-50 are being rejected under 35 U.S.C. 102(e) as being anticipated by Kedar et. al (P/N 6,165,778).

Applicants suggest that Kedar fails to disclose receiving first user input defining a first mapping that defines a gradient distribution and input defining a second mapping and second distribution and modifying a visual representation to include a visual indication of determined amounts of the first and second chemicals or mixtures of chemicals.

Kedar, at Fig. 33 and col. 8, lines 59-67, discusses a GUI with user commands, which controls the operations of the synthesizer. Kedar at col. 91, lines 8-20, discusses how the GUI allows for manual selection and control for the synthesizer, which is a device for generating tagged chemical libraries and synthesizing collections of diverse molecules, see col. 9, lines 45-54. Kedar at col. 91, lines 29-38, discusses the submenu options, which are associated with the macros options and control the synthesizer. It is user input, both first user input and second user input etc., through selecting options for the macros, which control the synthesizer. Therefore, the user defines the macros, which are then used to define the synthesis. For example, Kedar at col. 14, lines 25-59, discusse a multiple step coupling reaction where the coupling occurs in each reaction vessel for a first monomer and a first tag using different monomers and tag combinations in each different reaction vessel, which represents selecting first chemicals or combinations that are gradiently distributed to each reaction vessel. In addition, a second coupling step occurs through coupling a first monomer to a second monomer and a second tag, which represents a second user input and a second mapping. Therefore, the user determines which monomers will be distributed to which reaction vessels, which is done through user input and defining the macros that

control the synthesis. Furthermore, Kedar at col. 96, lines 10-67 and col. 97, lines 1-18, discusses a detection tee, which detects a number of beeds that has been selected to be distributed to each of the reaction vessels, but dispenses anywhere from 1 to 5 beads at a time, which represents a minimum and maximum. Kedar at col. 91, lines 66-67 and col. 92, lines 1-13, discusses how the user chooses the reaction vessels and the time to fill the reaction vessels, which represents an option for filling the reaction vessels gradiently. Kedar, at col. 93, lines 60-65 discusses displaying what is in each of the vessels as the user selects appropriate reaction chemicals, which represents modifying a visual display to represent the chemicals or combination thereof, which are in each of the vessels.

Claim Rejections - 35 USC § 103

Maintained with respect to the following claims

Applicant's suggest that Agrafiotis uses a mapping scheme for analyzing compounds and not for assigning amounts of the components to destination cells that represent physical locations. However, as Agrafiotis may use a mapping scheme for a different purpose, the invention does provide a generic and adaptable interface for use in a different application as stated below. Additionally, it is Schultz, at col. 3 and 4 and as stated below, that describes a mapping scheme for assigning amounts of chemicals to destination cells that represent physical locations. Therefore, the interface of Agrafiotis is being combined to use the mapping scheme and combinatorial library design of Schultz and Flavin and the rejection is maintained as reiterated below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-9, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flavin et al. (P/N 6,044,212); taken in view of Schultz et al. (P/N 6,004,617); taken further in view of Agrafiotis et al. (P/N 6,295,514).

The claimed subject matter is drawn to a computer-implemented method for designing a library of materials. The method implements the use of a graphical user interface, which allows the user to control the parameters and design.

In the abstract Flavin et al. summarizes that the disclosed invention is directed to combinatorial chemistry in a computer controlled design method as is also the purpose of the above listed instant claims. In column 4, lines 7-14, the combinatorial synthesis

complexity is reinforced by citing the number of reagents as being in the hundreds etc. Prior to reagent dispensing the software program, resident in either RAM or ROM, first designs or determines the initial values of reagent concentrations and the type of reagents for each well as summarized in column 5, lines 24-28. This is a generic statement that lacks details as to what these initial values may be but clearly is directed to combinatorial library preparation. Such a generic setting up of initial values motivates someone wishing to perform such a procedure to look to wherever combinatorial library reagents, values, etc. would be found which must be in other references in the prior art since no significant detail is supplied for such initial values etc. are present in the reference. The reagent values and types are stored in a parameter look-up table in the computer memory as stated in column 5, lines 46-51. Additionally, Flavin et al. states in col. 2, lines 44-46 "The synthesizer 12 further includes a robotic arm assembly 26 which has pipetting capability for selectively adding quantities of one or more reagents to the wells 16." "The reagent values and types of reagents is either based on operator input or based on the optimization scheme described subsequently." Col. 5, lines 49-51. Several optional automatic repetitive reaction runs and analyses are then disclosed in the reference. The displaying of the scores and data from the library of reaction materials is disclosed in column 8, lines 37-41, which also notes that each step in the methodology can be updated for the operator to be informed of the current reaction. The reference is focused on the computer design of reactions for a combinatorial library and lacks significant detail regarding the various library material components that may be utilized as well as the output of data or scores regarding the libraries made thereby.

Thus, practices from the prior art must be performed and are therefore motivated for both the details of combinatorial library reagents as well as data output for a library that is prepared. Flavin et al. does not show details of a library preparation or a graphical display for controlling preparation.

Schultz et al. is a reference which focuses on these additional details which are needed for combinatorial library preparation and data display. It is noted that Schultz et al. also deposits library material at regions on a substrate or destinationts) as summarized in column 7, lines 13-48, as does the instant invention. A wide variety of material combinations are optional in Schultz et al. for library preparation as set forth in column 7, line 56, through column 9, line 40, which are clearly inclusive of a variety of chemical entities such as utilized in combinatorial libraries. The preparation of the libraries of Schultz et al. occurs via a number of options, however, the robotic or automated methodology as of Flavin et al. is suggested and motivated in column 12, lines 30-38, of Schultz et al. The utilization of gradient application of source materials for library preparation is cited at several locations throughout Schultz et al., for example, at column 10, lines 30-33, column 11 , lines 8-1 1, column 33, lines 17-35, and in a specific example in Figures 18, 19A, and 19B. A variety of reaction conditions for various library regions is also described, for example, in columns 3-4, bridging paragraph. The Figure 18, 19A, and 19B description is of particular note because they depict both gradient deposition of library materials in a rectangular region as well as graphical display of the representations or analyses of the library so prepared.

Agrafiotis et al. is also directed to computer design of a set of compounds as a

combinatorial library ("The user interface modules 108 enable users to organize compounds as collections (representing, for example, a combinatorial library" col. 4, lines 30-34)) via non-linear mapping as summarized therein in column 1, line 21 through column 2, line 34. It is noted that the gradient practice of the instant claims are also a non-linear compound mapping scheme. Agrafiotis et al. additionally summarizes a graphical user interface for such design practice as summarized in column 15, line 1, through column 17, line 43. The updating or modifying ability of such an interface is described in column 16, lines 45-59, as also instantly claimed such as in claim 1, last 2 lines. Additionally, "the present invention enables the chemical data visualization and interactive analysis module 104 to interact with a number of other modules, including but not limited to one or more map viewers 112. NMR (nuclear magnetic resonance) widget/module 130. structure viewers 110, MS (mass spectrometry) widget/module 134, spreadsheets 136, QSAR (Quantitative Structure-Activity Relationships) module 138, an experiment planner 140, property prediction programs 142, active site docker 144, etc. These modules communicate with the chemical data visualization and interactive analysis module 104 via the communication medium 118." Col. 4, lines 51-63. For example, Agrafiotis et al. indicates that someone skilled in the art appreciates the flexibility etc. of such a user interface in column 17, lines 2-11. This is reasonably interpreted as generic motivation and suggestion to utilize such an interface in order to obtain the benefits of flexibility etc. as set forth in Agrafiotis et al.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the Flavin et al. automated/robotic combinatorial

design method which requires details of library preparation and data display with a reference such as Schultz et al. which supplies details of library preparation, such as gradient practice, as well as graphical display of library representations to result in the practice of the instant invention.

Flavin et al. shows a general application of automated analysis of combinatorial libraries. This broad application of automated analysis implicity incorporates an analysis of similarities and dissimilarities in a combinatorial library.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize a graphical user interface, motivated by benefits such as flexibility etc. as set forth in Agrafiotis et al. to improve on the combinatorial library design practice of the combination of Flavin et al. with Schultz et al. to result in the practice of the instant invention.

OBVIOUSNESS TYPE DOUBLE PATENTING

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Regarding use of the specification in obviousness-type double patenting rejections, the MPEP states in section 804:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 1, 3-9, 12-14, 19, 21, 23, 29, 37, 39-45, 48-50, 55, 91, 97, and 99-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 9-12, 27-31, 33-36, 55-63, 65-74, 76-104 of U.S. Patent No. 09/174856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application No. 09/174856 are generic with respect to combinatorial libraries of instant claim 1. Copending application No. 09/174856 shows the reference to combinatorial libraries on page 1 of the specification.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No Claim is Allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571)-272-0514.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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